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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/748,466	12/26/2000	Deguang Zhu		3400
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EXAMINER

LAMM, MARINA

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/748,466
Filing Date: December 26, 2000
Appellant(s): ZHU ET AL.

Jay P. Lessler
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 4/19/04.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. Therefore, it is presumed that there are none. The Board, however, may exercise its discretion to require an explicit statement as to the existence of any related appeals and interferences.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The amendment after final rejection filed on 4/19/04 has been entered.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows: The rejection of Claims 5 and 9 under 35 U.S.C. §102(b) as being anticipated by Weiner (US 5,200,393) has been withdrawn in view of the Applicant's arguments.

(7) Grouping of Claims

The rejection of claims 5, 9-14 and 16 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5,145,679	HINSON	9-1992
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(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1. Claims 5, 9-14 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Hinson (US 5,145,679).

Hinson teaches a method for treating skin conditions such as skin lesions, skin rash, etc. comprising topically applying to the surface of the skin a topical emollient which is a solution consisting essentially of glucose and insulin, wherein insulin is present as a concentration of 0.06-2 units/ml. See Abstract; col. 1, lines 13-17; col. 2, lines 34-36. The compositions of Hinson can be applied to the skin or scalp. See Examples. With respect to the limitations recited in the preambles of Claims 5 and 9, it is noted that newly discovered results of known processes (i.e. topically applying a compositions consisting essentially of insulin to the skin or scalp) are not patentable because such results are inherent. Since the method step (i.e., topically applying a

compositions consisting essentially of insulin) is the same, the result (i.e., increasing skin firmness, etc.) will inherently be the same.

(11) Response to Argument

Since the rejection of Claims 5 and 9 under 35 U.S.C. §102(b) as being anticipated by Weiner (US 5,200,393) has been withdrawn in view of the Applicant's arguments, only those arguments pertinent to the outstanding rejection over Hinson will be addressed. See pp. 5-6 of the Brief.

The Applicant argues that Hinson's compositions are used for the treatment of circulatory induced skin lesions (such as those in diabetic patients), which are *pathological* changes of the skin. The Applicant further argues that, in contrast, the instant method is used for the treatment of *physiological* changes in the skin. The Applicant also argues that the definition of the "skin" as used in the instant specification excludes the pathological changes in the skin taught by Hinson. The Applicant refers to p. 6, lines 11-15 for the distinctness of the terms "wounds", including "lesions", and "skin". In response, the Examiner was unable to find a clear definition of "skin" in the instant specification. The aforementioned section of the specification recites that both natural, synthetic and recombinant insulin can offer the same or similar effects "on skin, scalp, hair and wound," but does not contain a clear definition of either the term "skin", "lesion" or "wound." On the contrary, the specification lists wound treatment and skincare in diabetic patients as possible uses of insulin and does not distinguish between treating "pathological" and "physiological" changes in the skin. See pp. 2-3 of

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the specification. It is further noted that the Hinson's method is not limited to wound treating and includes treating of skin rash. See Example 4 @ col. 3-4. Although the reference is silent about treating of aging skin or scalp, increasing skin firmness and elasticity, reducing lines and wrinkles, improving age spots, treating winter itch and improving sebaceous and sweat gland secretion, it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable. In re Woodruff, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). On this record, it is reasonable to conclude that the overlapping patient population is being administered the same active agent by the same mode of administration in the same amount in both the instant claims and the prior art reference. The fact that Applicant may have discovered yet another beneficial effect from the method set forth in the prior art does not mean that they are entitled to receive a patent on that method.


For the above reasons, it is believed that the rejections should be sustained.

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Respectfully submitted,

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Examiner
Art Unit 1616

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June 22, 2004

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